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# USFDA Red-flags Lack of Controls at Wockhardt Unit

## Written production & process control procedures had not been documented

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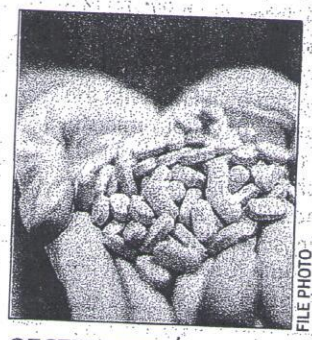
**ET Now:** The US Food and Drug Administration's inspection at Indian drug maker Wockhardt's plant at Shendra earlier this month found a series of violations, including lack of controls to ensure that only authorised personnel could make changes to records and a bag of unaccounted shredded documents in a laboratory.

Wockhardt's Shendra unit near Aurangabad, which supplies products to some developed markets, was inspected from January 4 to 12, ahead of initiating supplies to the US. The FDA had listed nine observations related to processes followed at the plant, which Wockhardt later clarified were not of a serious nature. The details of the observations were not known until now.

One observation noted by FDA investigators in Form 483 showed that appropriate controls had not been exercised over computers and related systems to ensure that changes in master production and control records are instituted only by authorised personnel, according to the regulator's document available with ET Now, the business news channel of ET.

The FDA observed that written production and process control procedures had not been documented at the time of performance. The FDA officials said they discovered one bag of unaccounted shredded documents next to a shredder machine located inside the microbiology quality control laboratory. The bag included indistinguishable controlled documents, signed laboratory worksheets and work reports containing uncontrolled notes about work being performed and schedule planning for the quality control testing laboratory.



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**OBSERVATIONS**

**In its inspection at Wockhardt's Shendra unit, FDA had made 9 observations related to processes followed at the plant**

The FDA made nine observations, for which appropriate reply would be submitted to the inspecting authority in due course, Wockhardt said in a stock exchange filing on January 15. Chairman Habil Khorakiwala said on January 19 that some of the observations could be addressed in the short term and a few may take a couple of months.

One observation in Form 483 signed by investigators Daniel J Roberts and Dipesh K Shah noted that the aseptic processing areas were deficient regarding the system for monitoring environmental conditions.

The report said procedures designed to prevent microbiological contamination of drug products purporting to be sterile were not established.

Regulatory